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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/752,423	BUNTINX, ERIK	
	Examiner	Art Unit	
	UMAMAHESWARI RAMACHANDRAN	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *64,65 and 68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *64,65 and 68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/4/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner notes the receipt of the amendments and remarks received in the office on 12/30/2009 cancelling claims 1-63, 66-67 and adding new claim 68 and amending claim 64. Claims 1 -63, 66, and 67 has been cancelled. Claim 68 has been added new. Claims 64, 65, 68 are currently pending and are being examined on the merits herein.

Response to Remarks/Arguments

The rejection of claims 1, 10, 64, 65 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn due to Applicants' cancellation and amendment of claims. However, Applicants' addition of new claim necessitated the modified ODP rejection given below. Applicants' arguments regarding the 112(1) enablement rejection have been fully considered but the rejection is maintained with respect to the active metabolites of SSRI compounds. Applicants arguments regarding the rejection of claims 1, 10, 64 and 67 under 35 U.S.C. 103(a) as being unpatentable over Bymaster et al. (IDS document: WO 98/11897) in view of Prinssen et al. (E J of Pharmacology, 388, 2000, 57-67) has been fully considered and found to be persuasive. Applicants' arguments regarding the 103 rejection of claims 1, 64 under 35 U.S.C. 103(a) as being unpatentable over Cremers et al. (U.S. 2003/0032636, effective filing date, Dec 6 1999) in view of Prinssen et al. (E J of Pharmacology, 388, 2000, 57-67) have been fully considered and found not to be persuasive. Applicants' addition of new claim necessitated the modified rejections given below. Accordingly, the action is made Final.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 68 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 82-84, 100, 101 of copending Application No. 10/580,962.

Claim 68 of the instant application is drawn to a method of for treating anxiety disorder comprising administering to a patient a compound such as pipamperone in a range between 5 and 15 mg and a second agent, a serotonin reuptake inhibitor.

Claims 82-84, 100,101 of the co-pending application ('962) teach a method for treating mood disorders or anxiety disorders comprising administering to a patient pipamperone, or a pharmaceutically acceptable salt thereof, in a dose ranging between 5 and 15 mg per day of the active ingredient, and administering said pipamperone simultaneously with, separate from or sequential to a second compound, to augment the therapeutic effect of said second compound or to provide a faster onset of the therapeutic effect of said second compound, wherein said second compound is selected

from the group consisting of: selective serotonin, nor-adrenaline and dopamine re-uptake inhibitors (SNDRI), selective serotonin and nor-adrenaline re-uptake inhibitors (SNRI) and selective serotonin re-uptake inhibitors (SSRI). The co-pending application further teaches escitalopram, fluoxetine etc to be a second agent.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both teach a method of treatment of emotional disorders such as anxiety disorder comprising administering pipamperone and a selective serotonin reuptake inhibitor such as citalopram as a second agent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections-35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 64 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating mood or anxiety disorders with a composition comprised of citalopram and pipamperone, does not reasonably provide enablement for treating anxiety disorder with all active metabolites of selective serotonin and nor-adrenaline reuptake inhibitors, chosen from the group consisting of citalopram, fluoxetine, paroxetine, sertraline, milnacipram and duloxetine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

See M.P.E.P. 2164.08. The reference of Meyer, J, Pharmacokinetics and Biopharmaceutics, 24, pp. 449-459, is used in this rejection.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in re Wands, 858 F.2d 731,8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (Wands, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (Wands, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary

While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to a method of treating an anxiety disorder comprised of pipamperone and SSRI compounds citalopram, fluoxetine, fluvoxamine, paroxetine,

sertraline, milnacipran and duloxetine. The claims also cite that the SSRI compounds include active metabolites of SNRIs. Thus, the claims taken together with the specification imply all active metabolites of SNRIs claimed can be used in a composition for treating anxiety disorder. However, the number of possible active metabolites of claimed SNRIs can be considerably large, and not all of the active metabolites would be expected to have the same biological activity. Additionally, it is known in the art that some metabolites can be more toxic than the parent drug, which would make their administration undesirable.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

The prior art teaches that pipamperone and citalopram are both useful in compositions for treating anxiety disorder. However, there is no such evidence in the prior art that all active metabolites of SNRIs claimed would also be effective. The prior art does provide evidence that active metabolites of parent drugs can vary considerably, in terms of potency and toxicity, as taught by Meyer (p. 450, first paragraph). Furthermore, Meyer et. al. also teaches that drug metabolism is also genetically dependent, and that major differences can exist between different individuals' abilities to metabolize drugs (p. 453). Age, lifestyle, health, and other environmental factors can also have an effect on personal drug metabolism (p. 453). Therefore, it is unlikely that all active metabolites would have similar potency, and toxicological data as the parent compounds. Therefore, while studies are useful to determine which particular active metabolites would be expected to be beneficial, there exists unpredictability regarding

whether all active metabolites of compounds would have similar benefits of the parent compounds.

(5) The relative skill of those in the art:

The relative skill of one in the art would be high, such as that of an MD.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided guidance for citalopram and pipamperone for measuring pKi values of some test compounds and describes the foregoing pipamperone-citalopram treatment for depressive disorder clinical trial set up data. However, the specification does not provide guidance for all possible active metabolites of SNRIs claimed to be administered as a composition for treating anxiety or any of the disorders.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to the evidence of the prior art regarding active metabolites, and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims. The prior art teaches that considerable differences can exist between active metabolites and parent compounds regarding activity, metabolism, and toxicity. Therefore, not all active metabolites of SNRIs claimed would be expected to be as effective as the parent compounds. As such, one of ordinary skill in the art would be

burdened with undue experimentation to determine specifically which active metabolites would be effective and safe for treating anxiety disorders

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 64 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cremers et al. (U.S. 2003/0032636, effective filing date, Dec 6 1999) in view of Prinssen et al. (E J of Pharmacology, 388, 2000, 57-67).

Cremers et al. teaches the use of compositions of compounds having serotonin reuptake inhibiting activity and 5-HT2C antagonistic activity for the treatments of depression and other affective disorders such as anxiety disorder (see abstract, p 8, claims 1-12). Cremers et al. teaches compounds such as citalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, milnacipran and duloxetine as SSRI compounds

(para 0068, p 8, claim 5). The reference teaches that the 5-HT2C antagonist in combination therapy may range from about 0.1 to about 150 mg/day, particularly from about 0.1 to about 100 mg/day and more particularly from about 0.5 to about 50 mg/day and even more particularly from about 1 to about 5 mg/day (para 0086). The reference teaches that 5-HT2C antagonists in combination with SSRIs, synergistically act to increase the level of extracellular serotonin and as applied to humans, this would imply a shorter onset of antidepressant effect in the clinic and an augmentation, or potentiation of the therapeutic effect of the serotonin reuptake inhibitor (SRI) (para 0015). The reference teaches subcutaneous administration of citalopram, 10 μmol/kg.

The reference does not pipamperone as the 5-HT2C antagonistic compound in the composition in a method of treating a disorder such as anxiety.

Prinssen et al. teaches pipamperone, an antipsychotic compound as one of the 5-HT2C antagonistic compound. It is known in the art that Dipiperon (pipamperone) is useful in the symptomatic treatment of serious forms of agitation and anxiety (Dipiperon (Applicant cited IDS reference, manufacturer sheet).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have administered a SSRI compound such as citalopram along with pipamperone because of the prior art teachings of Cremers et al. Cremers et al. teaches use of compositions comprising SSRI compounds such as citalopram with compounds of 5HT2C antagonistic activity for treating anxiety disorders. It is known in the art that pipamperone, an antipsychotic agent is useful for treating anxiety disorders and also has 5HT2C antagonistic activity. One having ordinary skill in the art would

have been motivated to administer a SSRI compound such as citalopram along with pipamperone in expectation of success and in achieving therapeutic benefits in treating anxiety disorders as both SSRI and pipamperone are taught in the prior art to be useful for treat anxiety disorders and Cremers in particular teach the use of combination of an SSRI compound with a compound of 5HT2C antagonistic activity in treating anxiety disorders. The idea for using both the compounds in combination therapy flows logically from their having been used individually in the prior art. One having ordinary skill in the art would have been motivated to add a 5HT2C in combination with an antidepressant, SSRI compound to augment or potentiate the therapeutic effect of SSRI. It would have been obvious to one having ordinary skill in the art to have administered 5 -15 mg pipamperone in combination with an SSRI agent in treating anxiety disorder because Cremers et al. teaches 5-HT2C antagonist in combination therapy for treating disorders such as anxiety in the range from about 0.1 to about 150 mg.

Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cremers et al. (U.S. 2003/0032636, effective filing date, Dec 6 1999) in view of Prinssen et al. (E J of Pharmacology, 388, 2000, 57-67) as applied to claims 64 and 68 above and further in view of Bymaster et al. (IDS document: WO 98/11897).

Cremers et al. and Prinssen et al. teachings discussed as above.

Cremers et al. teaches subcutaneous administration of citalopram, 10 μmol/kg. The reference does not explicitly teach the amount of citalopram to be 10 -40 mg as claimed.

Bymaster et al. teaches a method of treating a patient suffering from mild anxiety states comprising administering a first component a atypical antipsychotic agent in combination with effective amount of a serotonin reuptake inhibitor such as citalopram, fluvoxamine, paroxetine, sertraline, milnacipran and duloxetine. The reference teaches in p 16, lines 1-10, the dosages of citalopram: from about 5 to about 50 mg once/day (p 16. lines 1-2) and antipsychotic agents in the range of 0.25 to 100 mg/day depending on the antipsychotic drug administered (See p 15, lines 14-25).

Accordingly, it would have been obvious to one having ordinary skill in the art to administer an amount of 10-40 mg of citalopram as claimed in treating anxiety disorder because Bymaster et al. teaches administration of such dosage amount of SSRI compound, citalopram with an antipsychotic agent would be useful in treating anxiety disorder. One having ordinary skill in the art at the time of the invention would have been motivated to administer such dosages in expectation of success and in expectation of therapeutic benefits.

Response to Arguments

Applicants in the response to the office action describe the dose effect of pipamperone and its effect as a sedative neurolepticum at higher doses. Applicants' argue that the invention does not involve a mere optimization of dosage by routine experimentation and the prior art teaches away from using a low dose. In response, Dipiperon document teaches giving initial dose of 20 mg/day for children for symptomatic treatment of serious forms of agitation and anxiety. The document teaches that elderly start with half the initial dose which will be 20 mg. Cremers et al. teaches the

use of compositions of compounds having serotonin reuptake inhibiting activity and 5-HT2C antagonistic activity for the treatments of depression and other affective disorders such as anxiety disorder. Synergy between drugs in a combination therapy is a well known concept and combination therapy has been used widely in various fields of medicine. Cremers reference teaches that 5-HT2C antagonists in combination with SSRIs, synergistically act to increase the level of extracellular serotonin and as applied to humans, this would imply a shorter onset of antidepressant effect in the clinic and an augmentation, or potentiation of the therapeutic effect of the serotonin reuptake inhibitor (SRI). It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a 5-HT2C antagonist such as pipamperone in combination with an SNRI compound such as citalopram in a method of treating anxiety disorder from the teachings of Cremers and Dipiperon document. It would have been obvious to one having ordinary skill in the art at the time of the invention to have lowered the dosage of compounds in a combination therapy as synergy between drugs can be expected. Accordingly, it would have been obvious to one having ordinary skill in the art to try administering 15 mg of pipamperone in a combination therapy with an SNRI compound in treating anxiety disorder. One having ordinary skill in the art would have been motivated to reduce the dosages of the drugs in a combination therapy in expectation of achieving similar or better therapeutic benefits with reduced adverse effects.

Applicants' argue that pipamperone does not qualify as a drug to be combined with SSRIs according to the teachings of Prinssen and Cremers as according to

Prinssen a high dosage amount it required to achieve a clinically relevant effect. In response, Dipiperon (Applicant cited IDS reference, manufacturer sheet) clearly teaches in section "Clinical Particulars" that the drug is used for symptomatic treatment of serious forms of agitation and anxiety. The reference teaches adult doses of 40-80 mg and children initial dosages of 20 mg/day. The reference states that for the elderly start with half the initial dose which will be 20 mg according to the document. Accordingly, it has been shown that pipamperone can be given at low dose of 20 mg to children and adults to treat anxiety. Applicants' are claiming a dose of pipamperone 5- 15 mg/day along with an SSRI. One having ordinary skill in the art at the time of the invention would have been motivated to give a lower dosage of pipamperone, say 15 mg in a combination therapy with an SSRI agent is to increase the efficacy and reduce adverse/side effects.

Applicants have submitted supporting documents Wade et al 2009 abstract and Buntinx et al. document to report that a very low daily dose of pipamperone added to the selective serotonin re-uptake inhibitor citalopram provided superior antidepressant effects and less discontinuation compared with citalopram alone. Applicants have shown unexpected results only with respect to SSRI citalopram compound with low dose of pipamperone. To overcome 103 obviousness the unexpected results must commensurate in scope. The unexpected results presented by the Applicants' do not commensurate in scope with the claims because the claims are broad with respect to the SSRI inhibitors (known and yet to be discovered) and their dosages (claim 68) and the different types of SSRI's and dosage ranges of SSRI claimed (claim 64). The

unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles,* 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr,* 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder,* 173 USPQ 356 (CCPA 1972). Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. In re Clemens, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980). See MPEP 716.02(d).

Conclusion

No claims are allowed.

Applicant's addition of new claim necessitated the modified rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627